REMARKS/ARGUMENTS

Claims 4-5 are amended by this response. No claims are canceled or added. Accordingly, claims 1-28 remain pending in the instant application.

Embodiments in accordance with the present invention relate to methods and software programs allowing the outputs of models for complex phenomena such as clinical trials and drug performance, to be interrogated, explored, and viewed by members of a drug development team. Such models are typically constructed utilizing available data such as data from actual clinical trials, data from competitors, and data from the published literature.

Exploration of models is shown and described generally in connection with Figure 3 of the instant application.

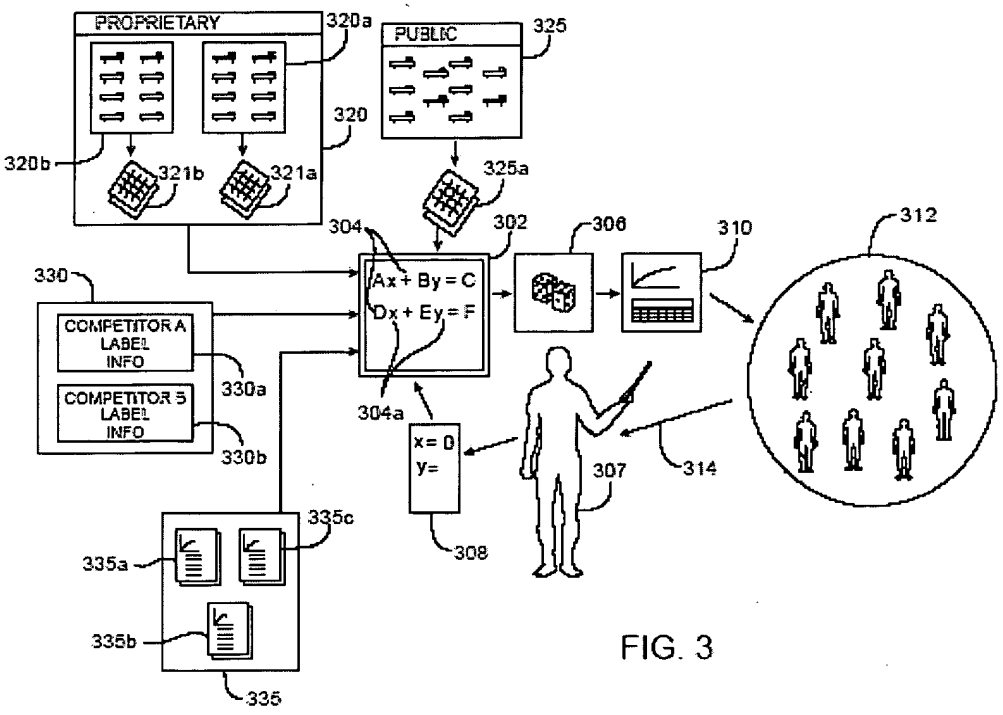


FIG. 3

In particular, Figure 3 shows that model (302) may rely upon a plurality of sources of information (320, 325, 330, and 335) to generate output (310) to audience (312), based upon conditions (308) input by human expert (307) familiar with the structure of the model. The audience then communicates with the human expert to modify the input conditions to gain further insight from the model.

In connection with Figure 3, the instant application emphasizes:

> the audience/model feedback mechanism of the conventional system is dominated by the human expert. The human expert must translate abstract pharmacological concepts relevant to the audience into concrete mathematical relationships relevant to the model. This translation process not only slows audience/model feedback, but also creates a distance between the audience and the model, so that the audience may not develop a deep understanding or intuition about the drug candidate's behavior as predicted by the model. (Emphasis added; **¶[0089]**)

Accordingly, Figure 10B shows automation of the model exploration function utilizing a metadata file in accordance with an embodiment of the present invention:

> left half 1000 of Figure 10B represents raw simulation output by a model in an arbitrary format that only implicitly reflects the hierarchical structure of the model. The right half 1002 of Figure 10B represents the same data organized into the DMX format explicitly encoded to reflect the hierarchical structure of the model. (**¶[0120]**)

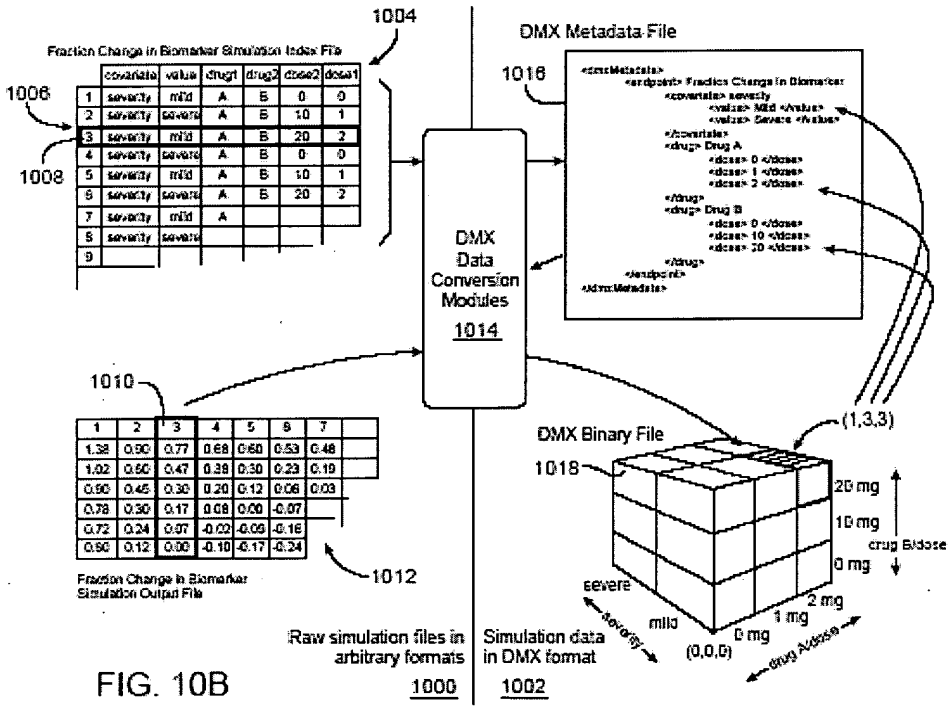


FIG. 10B

[0124] The DMX metadata file 1016 is a replacement for the simulation index file 1004. Index information contained in files 1004 and 1012 is extracted and utilized to encode the metadata file 1016. The data structure implicitly imparted

> to file 1004 by the hierarchical model organization, is thus transformed into an explicit, ordered XML tree structure. (Emphasis added)
>
> **[0125]** DMX Binary file 1018 is a replacement for simulation output file 1012. Data contained in the original output file 1012 is converted in binary file 1018 into an n-dimensional hypercube structure. The geometry of this structure matches the tree structure of metadata file 1016. As a result of this transformation, the location in the binary file of simulation output corresponding to a given input vector, may be read from the model structure explicitly reflected in metadata file 1016. (Emphasis added)

Pending independent claims 1 and 26 accordingly recite as follows:

> 1. A method of representing performance of a drug candidate, the method comprising:
>
> . . . extracting the index information from the raw data;
>
> referencing the extracted index information to generate a metadata file, a structure of the metadata file explicitly reflecting a hierarchical structure of the model;
>
> referencing the metadata file to convert the raw data file into a binary file, the metadata file explicitly identifying locations of treatment scenario information types and the output performance information types within the binary file . . . . (Emphasis added)
>
> * * *
>
> 26. A computer system comprising a processor and a memory storing code to operate the processor, the code comprising,
>
> a parser module configured to receive raw data output by a model of drug candidate behavior, and to generate a metadata file encoding outputs and related inputs of the model based upon index information extracted from the raw data;
>
> a data transfer module configured to convert the raw data into a binary file organized to match a structure encoded in the metadata file . . . . (Emphasis added)

In the latest office action, the Examiner rejected all of the claims as lacking utility under 35 U.S.C §101. These claim rejections are overcome as follows.

The Examiner is respectfully directed to the guidelines for determining compliance with the Utility requirement that are set forth in the Manual of Patent Examining Procedure (MPEP). Specifically, MPEP 2107(II)(B)(1) emphasizes:

> **2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement**
>
> If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would

> be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (Emphasis added)

Here, the instant specification describes in substantial detail the problem addressed by the claimed embodiments. For example, in connection with Figure 10B shown above:

> **[0118]** Output file 1012 contains the resulting simulated outputs, and when combined with the inputs, the original hierarchical structure of the model may be inferred. However, such implicit determination of model structure from inputs/outputs is not generally within the ability of a non-expert. Rather, the modeling expert must review and then present the results in a manner which allows an audience to recognize the model's hierarchical structure: here, behavior of the drug candidate is modeled based upon the three specific input variables. Such necessary conventional intervention by the human expert interferes with the audience's ability to meaningfully interact with the modeling results, and to develop intuition regarding the model's structure and operation.

The instant specification then goes on to unequivocally express the utility achieved by the claimed embodiments:

> **[0126]** Review of the structure of DMX data files 1016 and 1018 reveals that taken together, they locate treatment types and corresponding simulated results in a manner which explicitly reflects the hierarchical structure of the original model. Specifically, in this conceptual example limited to 3 dimensions for the convenience of communication, binary file 1018 comprises a structure having X-, Y-, and Z- axes corresponding to each of the input variables. In this manner, the original structure of the model may be readily discerned from the simulated data. (Emphasis added)

Based at least on the above, there can be no reasonable question that Applicants have indeed established sufficient practical purposes for the claimed invention, purposes that would readily be recognized by one of ordinary skill in the art. Accordingly, the burden imposed by the Examination Guidelines set forth in MPEP §2107 has clearly been met, and continued rejection of the pending claims as lacking utility, is improper.

The Examiner also rejected all of the formerly pending claims as indefinite under 35 U.S.C §112. These claim rejections are overcome as follows.

As a threshold matter, the Examiner is respectfully reminded of the wide latitude afforded an Applicants in their choice of terms utilized to defining the invention:

> A fundamental principle contained in 35 U.S.C. §112, ¶2 is that applicants are their own lexicographers. . . . Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim . . . . (Emphasis added; MPEP §2173.01)

Accordingly, the MPEP directs the Examiner to:

> allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. (Emphasis original; MPEP §2173.02)

Here, the Examiner has relied upon a litany of claim terms as forming the basis for the indefiniteness rejections. For example, in claim 1 the Examiner has cited "raw data generated by a model", and inquired whether generation of such raw data is intended to be an active method step. Applicants respectfully respond that as described in detail in the above application, embodiments in accordance with the present invention utilize the raw model data as a starting point. Accordingly, while the raw model data is present, this raw data need not necessarily be generated by the party who is practicing the pending claims.

The Examiner has also cited the phrase "explicitly reflecting a hierarchical structure model" of claim 1, as a source of indefiniteness. Applicants are unable to locate this precise language in claim 1. Claim 1 does recite:

> . . . referencing the extracted index information to generate a metadata file, a structure of the metadata file explicitly reflecting a hierarchical structure of the model . . . . (Emphasis added)

Applicants respectfully respond that the generation of a metadata file explicitly reflecting a hierarchical structure of a model, is amply described throughout the instant specification, most particularly in **¶[0121]** and **¶[0124]** describing Figure 10B reproduced above. At least this portion of the instant specification illustrates and describes an example wherein an XML Tree structure of the metadata file explicitly reflects the vector structure of the model.

The Examiner has further cited the limitation of "referencing index information" as lending uncertainty to claim 1. Again, however, this element of the claimed embodiments is amply discussed in the instant specification, particularly in connection with the example of

Figure 10B at **¶[0124]**, wherein index information of the raw data from the model is referenced to create the XML Tree structure of the metadata file.

The Examiner has further inquired whether this "referencing of index information", or the other steps of generating the metadata file, converting the raw data, and identifying a subset. are active method steps. Applicants respond that each of the four steps cited by the Examiner are indeed affirmatively recited elements of the claimed embodiments.

The Examiner has also cited identification of a binary file relevant to a user selection imparting indefiniteness of claim 1. Again however, the specification also contains discussion of this step. See Figure 9 and accompanying text at least at **¶[0108]-[0109]**.

Claims 4-5 stand rejected as indefinite owing to use of the term "one of". Claims 4-5 have now been amended to replace "one of" with "or" in the manner indicated.

The Examiner also rejected independent claim 26 as indefinite based upon the referencing of metadata, and the relevance of user input to binary files, as discussed above in connection with claim 1. As indicated above, Applicant maintains the definiteness of these claim terms in claim 26 based upon their description in the specification, and the reasonableness standard set forth by the MPEP.

Turning now to address rejection of the pending claims based upon alleged prior art, the Examiner has rejected the pending claims as obvious under 35 U.S.C §103, based upon a number of different reference combinations. These obviousness rejections are overcome as follows.

As a threshold matter, the Examiner is reminded that in order to establish a prima facie case of obviousness:

> there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (MPEP 2143).

Such teaching or suggestion to make the claimed combination must be found in the prior art, not in applicant's own disclosure. In re Vaeck, 947 F.2d 488 (Fed.Cir. 1991).

Here, all of these reference combinations relied upon by the Examiner include U.S. patent no. 6,457,017 to Watkins et al. ("the Watkins Patent"). The Watkins Patent relates generally to an information management system including an indexing subsystem and a document management subsystem. However, there is absolutely no teaching in the Watkins Patent

regarding management of information generated by a complex modeling, never mind modeling of drug behavior. In particular, the Watkins Patent fails to include any teaching or even suggestion to generate a metadata file from raw data index information, in order to reflect a structure of the model responsible for producing the raw data.

In an effort to provide this absent teaching, the Examiner has combined the Watkins Patent with several other references, including U.S. patent no. 5,808,918 to Fink ("the Fink Patent"), and U.S. patent no. 6,108,635 to Herren et al. ("the Herren Patent'). Neither of these patents, however, contains any suggestion to motivate their combination with the Watkins Patent.

Specifically, the Fink Patent describes a model of the activity of biological systems at a variety of different levels. However, the Fink Patent contains no teaching to create from the raw data output from the model, a metadata file reflecting the model structure. Indeed, the Fink Patent teaches away from any such suggestion, emphasizing the role played by experts, rather than non-experts, in utilizing the model:

> Once the model has generated satisfactory behavior under a variety of healthy, diseased, treatment, and patient biologies, it can be delivered to the targeted users for examination by experts. (Emphasis added; col. 11, lines 54-57)

As for the Herren patent, this reference also describes modeling of biological processes, but again fails to teach, or even suggest, the desirability of generating from raw data, metadata reflecting the structure of the model. In particular, while the Herren Patent describes a well-developed interface for allowing a user to provide inputs to the model, the Herren Patent provides little or no recognition of the value of having a user intuit the structure of the model without assistance from an expert. Indeed, the Herren Patent makes repeated reference to the use of "expert knowledge" and "expert systems" in interpreting the results produced by the model.

Of course, the instant application provides ample teaching regarding the generation of a metadata file reflecting a structure of the model. However, the Examiner is respectfully reminded that any suggestion to combine references must be found in the prior art, and not be based upon applicants' own disclosure:

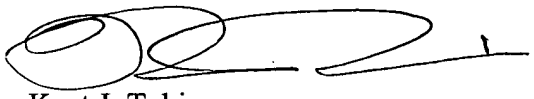
> The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However,

> impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (Emphasis added; MPEP 2142)

Here, the Watkins Patent and Fink and Herren Patents relied upon by the Examiner provide absolutely no motivation for their combination. Resort by the Examiner to Applicants' own disclosure to provide motivation or suggestion for combination is strictly prohibited as impermissible hindsight. And as such, the instant obviousness rejections are improper and should be withdrawn.

Based at least upon the failure of the references relied upon by the Examiner to provide motivation for their combination, it is respectfully asserted that the pending claims cannot be considered obvious. Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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